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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PATENT OPERATIONS

515-4210

In re Application of: Alessandra PAVESIO Group Art Unit: 1911 Massimo DONA' Examiner: Jones, D.C. Lanfranco CALLEGARO Serial No.: 09/700,142 Filed: November 9, 2000

BIOMATERIALS CONTAINING HYALURONIC ACID DERIVATIVES IN THE FORM OF THREE-DIMENSIONAL STRUCTURES FREE FROM CELLULAR COMPONENTS OR PRODUCTS THEREOF FOR THE IN VIVO REGENERATION OF TISSUE CELLS

> New York, NY 10036 August 13, 2002

Commissioner for Patents Washington, DC 20231

## RESPONSE TO REQUIREMENT FOR THE ELECTION OF SPECIES

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In response to the requirement for the election of a species, the applicants elect Group (a), which is the esters of hyaluronic acid which are esterified with: (i) aliphatic, (ii) aromatic, (iii) arylaliphatic, (iv) cycloaliphatic and (v) heterocyclic, with traverse.

The claims readable on the elected species are claim 24 (in part), claims 25-29 and claims 32-35.

The Examiner is asked to reconsider the requirement for the election of species because there is unity of invention in the claims of the present application and as such there is no basis for requiring the election of a species.

The present application is the U.S. National Phase of an International Patent Application filed under the Patent Cooperation Treaty. Thus the unity of invention of the claims must be determined under PCT

Rules 13.1 and 13.2.

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Claims 1 and 24 include a plethora of species, i.e. various hyaluronic acid derivatives, but there is a common inventive concept which unifies the species identified by the Examiner.

In fact, in the present invention there exists a technical relationship among the different species identified by the Examiner, i.e. the various hyaluronic acid derivatives, involving the same "special technical feature", which is recognized under the PCT Rules as requiring that a unity of invention be recognized.

The various hyaluronic acid derivatives included in claims 1 and 24 of the present application are all made in the form of three-dimensional structures that enclose communicating hollow spaces created by pores and/or fine fibers or micro-fibers entangled together. The particular structure of the claimed hyaluronic acid derivatives induces tissue regeneration, in the absence of cellular components or products thereof (see the text of the present application at page 3 line 27 - page 4 line 28).

The particular structure of the hyaluronic acid derivatives, which is common to all the claimed derivatives provides the claimed biomaterial with the ability to create an extracellular environment and stimulates the regeneration of tissues without requiring any cellular component.

This represents an unexpected and advantageous advance over the prior art, wherein only biomaterials containing cellular components were available for the use in tissue regeneration, thus requiring long and complex cultivation steps before transplantation to the site requiring tissue regeneration. In addition, expensive storage procedures such as cryopreservation (see present application at page 3, line 17 and ff.).

In other words, among the different species identified by the Examiner, i.e. the various hyaluronic

acid derivatives, there exists a technical relationship, i.e. the three-dimensional structure above described, that involves a "special technical feature" because this particular structure renders the present biomaterial advantageous over the prior art biomaterials. Furthermore, all the different species identified by the Examiner are hyaluronic acid derivatives, having the same desirable chemical and physicochemical characteristics peculiar to the polysaccharide chain of hyaluronic acid, such as biocompatibility and the ability to be useful in various tissue repair processes. All of the claimed derivatives may be processed in the particular three-dimensional structure illustrated above.

For these reasons, it is requested that the species election requirement be withdrawn and an action be issued on all of the claims.

Respectfully submitted,

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